July 13, 2018

The Honorable Alex Azar  
Secretary  
US Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

Secretary Azar,

The American Academy of Neurology (AAN) is the world’s largest medical specialty society representing more than 34,000 neurologists and clinical neuroscience professionals. The AAN is dedicated to promoting the highest quality patient-centered neurologic care. A neurologist is a physician with specialized training in diagnosing, treating, and managing disorders of the brain and nervous system. These disorders affect one in six people and include conditions such as multiple sclerosis, Alzheimer’s disease, Parkinson’s disease, stroke, migraine, epilepsy, traumatic brain injury, ALS, and spinal muscular atrophy.

The annual cost of treating neurologic disease in the United States exceeds $500 billion, and prescription drugs for neurologic conditions are some of the most expensive on the market. Medications prescribed by neurologists accounted for $5 billion in Medicare Part D payments in 2013, which trailed only internal medicine and family practice among specialties.1 High drug prices create unnecessary challenges for neurologists to deliver accessible and affordable care to their patients. We appreciate the opportunity to comment on potential solutions to these challenges.

The Administration’s blueprint to lower drug prices explores many actions and we are encouraged by the attention that your office has paid to this important issue. However, pharmaceutical manufacturers alone set the price of medications and the problem is the price. Actions throughout the drug pricing system can improve components of this issue and we welcome the proposals in your blueprint as a starting point for change. The problem will never truly be solved, though, until manufacturers are held accountable for setting unaffordable prices. In addition to the ideas and concerns that follow, we urge the Administration to explore mechanisms to increase transparency in the prescription drug pricing process beginning with manufacturers and extending throughout the health care system.

Moving Part B Drugs to Part D Coverage Limits Access and Shifts Costs to Patients

The Centers for Medicare and Medicaid Services (CMS) should avoid moving Part B drugs to Part D. Many medications prescribed by neurologists are Part B drugs used to treat serious, complex, and chronic conditions that require intensive long-term management and may lack viable treatment alternatives like multiple sclerosis (MS). In contrast, Part D drugs are largely self-administered products available via traditional retail pharmacies. Many retail pharmacies lack the capabilities or willingness to

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dispense and deliver Part B drugs that require special handling, temperature-controlled storage, or timely access. The difference in complexities for these medications is significant and moving Part B drugs to Part D presents safety concerns for patients and physicians.

Evidence demonstrates that moving Part B drugs to the Part D benefit would increase costs for patients and reduce their access to medication. Shifting Part B to Part D would also increase monthly premiums for Part D beneficiaries as their coverage broadens to include more products. For some beneficiaries, out-of-pocket costs at the point of sale would also increase. A 2011 government-commissioned study found that, “as drugs move from Part B to Part D...costs for beneficiaries rise. The increase in out-of-pocket costs is an important concern in examining the effects of the proposed consolidation, as it could impede beneficiary access to needed medication.” A 2018 analysis also found that moving any high-cost drug therapies from Part B to Part D would result in higher out-of-pocket costs for many beneficiaries and put upward pressure on Part D premiums. Some beneficiaries could lose medication coverage entirely as not all Medicare beneficiaries are enrolled in Part D prescription drug coverage. Medicare would likely see only a small decrease in total spending by moving Part B to Part D, and any decrease would come at the expense of shifting significant costs to beneficiaries. Moving Part B drugs to Part D would ultimately negatively affect the quality of neurologic care for patients with chronic conditions.

The AAN Opposes Indication-based Payments

Indication-based reimbursement to providers has the potential to limit patient access to necessary drugs, create financial disincentives for physicians to provide the most appropriate treatment, and adversely affect the clinical management of patients. Defining a pharmacy benefit based on diagnosis may harm some patients in a diagnostic category in which a medication is known to have some benefit, but the effect is understudied. This is particularly common in neurology where drugs in various categories (e.g., anticonvulsants, antipsychotics, and antidepressants) are often prescribed for off-label use to treat a condition not supported by an FDA on-label indication. To ensure patients can access critical Part B therapies, physicians must be able to cover the costs associated with the purchase, storage, maintenance, replenishment, and handling of the medications. Cuts to the reimbursement rate for Part B drugs for certain indications could disadvantage physicians who furnish those medications for off-label use. In these situations, payment rates for some indications may be lower than acquisition costs.

If physicians are unable to offer Part B drugs due to indication-based payment rates, patients will suffer. Some patients may need to seek treatment in higher cost sites of service like hospital outpatient departments while physicians may be forced to prescribe suboptimal medications because the most appropriate option is not reimbursed. Indication-based payments create disparities for physicians and their patients as expensive therapies will only remain available in practices capable of absorbing the difference between the high acquisition costs and low reimbursement rates.

Under an alternative indication-based payment policy structure, CMS may be able to mitigate some of these issues by ensuring that each indication for a product is assigned its own Healthcare Common Procedure Coding System (HCPCS) code and its own Average Sales Price (ASP)-based payment amount. If each indication has its own ASP and code, payments for individual indications may better correspond to the acquisition cost.

Unless CMS can administer an indication-based payment policy that adequately accounts for acquisition costs, the AAN strongly opposes any Medicare Part B drug payment policy that creates significant financial disincentives to prescribe optimal treatment.

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2 Acumen, LLC. Estimating the Effects of Consolidating Drugs under Part D or Part B. August 2011.
4 Id.
Reimbursement Rates Capped at Inflation Would Limit Patient Access to Part B Drugs

The Fiscal Year ("FY") Budget of the U.S. Government ("FY 2019 Budget") proposes to limit the Average Sales Price ("ASP") portion of the physician payment for Part B drugs to the Consumer Price Index for all Urban Consumers ("CPI-U"). Under this proposal, CMS would reimburse providers for the cost of drugs at the lesser of either ASP+6%, or the inflation-adjusted ASP+6%. This change is intended to discourage drug manufacturers from increasing drug prices faster than inflation.

This proposal presumes that drug manufacturers would limit price increases of Part B drugs to the rate of inflation since raising the prices faster than the rate of inflation would increase the cost to physicians to an amount greater than the payment capped at the CPI-U. However, the proposal does not include a requirement that manufacturers limit price increases. Therefore, manufacturers could continue to raise drug prices faster than the rate of inflation even if reimbursement increases were capped. Under this proposal, it is possible that drug prices rising faster than inflation would be reflected in a physician’s acquisition cost but not in a physician’s reimbursement rate. CMS should not implement this proposal in any way that punishes physicians for manufacturer price increases. The AAN opposes the FY 2019 budget proposal provisions that would hold physicians accountable for manufacturer actions on drug prices.

The AAN is concerned that this proposal would negatively impact Medicare beneficiaries. Although the Administration may believe that capping the reimbursement rate on Part B drugs by the CPI-U would incentivize providers to switch to lower cost drugs, many neurologic diseases lack lower cost alternatives to expensive treatments. For multiple neurologic diseases there are a limited number of options, or a limited number appropriate for individual patient needs as in MS or epilepsy. In other conditions only one single therapy is available. If the cost to physicians exceeds the CPI-U capped payments for a Part B drug with no lower cost alternatives, physicians would be forced into the difficult decision to suffer a financial loss to provide the treatment or choose not to offer it to patients. This is an unreasonable choice that no physician should face.

Since 2005, physicians have been reimbursed for Part B drugs at 106 percent ASP (104.3 percent of ASP with sequestration cuts5). This payment rate was enacted to allow patients to access Part B drugs administered by the physician in the office setting. This rate strikes a balance that recognizes the provider’s costs associated with the purchase, storage, maintenance, replenishment, and handling of Part B drugs. To maintain this careful balance, CMS should continue to base the payment amount on ASP. Without this balance, physician acquisition costs could significantly exceed the Medicare payment. Physicians must be able to purchase, store, and manage an adequate inventory of medically necessary Part B medications to appropriately care for their patients. Without adequate reimbursement, it will be increasingly difficult for physicians to administer Part B drugs and patients will be required to seek treatment in higher cost sites of service. This proposal will likely reduce the number of physicians administering Part B drugs, which would limit patient access to necessary medications.

Although the proposed changes to reimbursement rates would threaten all physicians and their ability to furnish Part B drugs, the policy would have a disproportionate impact on small and solo physician practices as these physicians have less bargaining power and higher acquisition costs to purchase medications as well as smaller financial reserves to absorb the costs.

Rebates Impede Transparency and Increase Costs

The AAN supports the restriction or elimination of the use of rebates. The use of rebates artificially drives up drug list prices, rarely lowers the cost to consumers, and often masks efforts from payers and pharmacy benefit managers to push certain therapies for non-medical reasons. Out-of-pocket drug costs

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5 Sequestration cuts are 2% and apply to the 80% of the payment rate paid by Medicare, not the 20% beneficiary coinsurance. Therefore, starting with a payment rate of 106% of ASP, the payment rate after sequestration = (106% of ASP) [80% x 98% + 20% = (106% of ASP) (98.4%) = 104.3% of ASP.
for patients with neurologic conditions are some of the highest for all medications. High costs lead patients to abandon or ration their prescriptions, which impacts adherence, leads to preventable disease progression, and increases health care utilization.

Any discounts in the drug pricing process must be transparent and passed on to consumers. Consumers should be able to see how the price of their medication changes as it moves through the health care system and clearly understand the price at their point of access. The current drug pricing and rebate process is intentionally opaque and creates a system in which manufacturers, payers, and third-parties are incentivized to keep drug prices high even if it means that patients are unable to afford their medications.

**The AAN Opposes Direct-to-Consumer Advertising**

The US pharmaceutical industry in 2017 spent more than $6 billion in direct-to-consumer advertisements with more than half of that spending going to television ads. The US remains one of just two countries that permit direct-to-consumer pharmaceutical advertising. These ads bypass the physician and complicate patient relationships with their prescribers as they demand newer, more expensive, and often unnecessary or inappropriate treatments.

Advertisements lack the comprehensive information required to present the full scope of potential risks to patients, and patients benefit from the support of trained medical professionals when making decisions about medication. Proposals to include the list price in advertisements will do little to reduce costs or inform patients. The actual price paid by consumers varies widely based on insurance status and the inclusion of list price may further confuse patients. Moreover, this shaming tactic is unlikely to meaningfully reduce costs as it includes no enforcement mechanism for truly egregious prices and pharmaceutical manufacturers may simply normalize ultra-high list prices by including them in advertisements.

The AAN opposes direct-to-consumer advertising and encourages manufacturers to divert these funds to medical research and development.

**Site Neutrality Could Reduce Perverse Incentives**

Drug administration services are paid at a higher rate in the hospital outpatient department (HOPD) as compared to the physician office setting due to differences in payment systems: the Medicare Physician Fee Schedule determines payment in the physician office and the Hospital Outpatient Prospective Payment System (OPPS) in the HOPD. Despite the difference in sites, the services that the patient received in each setting (e.g., infusion or chemotherapy) are equivalent. However, the drug administration services are paid at different rates. Payment amounts for the drugs are the same in the physician office and the HOPD (ASP+6 percent), except for drugs acquired through the 340B program in certain HOPDs, which are paid at a lower rate.

Site neutrality would eliminate the site-of-service differential and create equal payment amounts for drug administration services in both settings. We support site neutrality and believe site of service selection should be based on clinical considerations and patient preference, not on payment differentials. The Medicare payment system should not include financial incentives to select certain sites of service when the actual service provided is equal in both settings.

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6 Kantar US Insights Data 2017. This total does not include spending on social media advertising.
Value-based Arrangements Should Be Carefully Considered

The AAN strongly supports policies that promote value throughout the health care system. CMS should carefully consider any proposals that tie drug cost or physician reimbursement to value determination. Many neurology patients with chronic, complex conditions require specific medications to manage the unique components of their disease, and there may be few medication alternatives. As a result, the determination of value for neurology medications is uniquely impacted by the high cost of these medications. It is challenging to determine universal value for medications that offer varying levels of efficacy in individual patients. Any determination of value for neurology drugs should prioritize patient access and appropriate treatments while avoiding financial penalties for neurologists when they are prescribing in accordance with specialty-specific standards of care. We encourage CMS to work closely with physician associations like the AAN to determine the value of neurology medications.

Further Study is Needed Prior to Implementing the Competitive Acquisition Program

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 stated that the Competitive Acquisition Program (CAP) must be phased-in beginning in 2006.\(^8\) CAP implementation was originally scheduled for January 1, 2006, and was then delayed until July 1, 2006. On September 10, 2008, CMS announced that as of the end of 2008 it would postpone further implementation of CAP.

Under the program, CAP-participating providers contract with a CAP vendor for the provision of drugs administered incident to a physician’s service.\(^9\) Prior to a patient visit, the physician would submit a drug order to the CAP vendor for the patient’s drugs. After the patient visit, the physician would submit a drug administration claim to CMS but would not submit a claim for the drug. The CAP vendor that had provided the drug to the physician would bill both the beneficiary and Medicare for the cost of the drug.

The AAN has serious concerns about the potential impact of implementing CAP for a second time given the limitations of the current statutory and regulatory framework. The initial implementation of CAP was a complete failure with only one participating CAP vendor and an insignificant number of CAP-participating physicians. Additionally, the CAP regulations were difficult to understand and did not provide adequate guidance for implementing and participating in the program. Before any resources are devoted to implementing CAP in the future, we recommend that CMS carefully reevaluate the prior issues with CAP and work closely with physician groups and other stakeholders to determine whether CAP design and implementation is feasible. This program should only be reinstituted in a way that allows physicians to efficiently deliver Part B drugs with no interference in patient access.

CMS Should Consult Physicians Before Implementing New Demonstration Projects

The AAN calls upon CMS to consult with physician specialty societies whose membership may be impacted by demonstration projects. Our experience with the 2016 Part B Drug Payment Model demonstration program illustrates the importance of advance outreach from CMS.\(^10\) Because physician groups weren’t consulted in the design and implementation stages, we were forced to react to mandatory models from the agency instead of offering substantive feedback on the elements of a demonstration program that would have the most value for physicians. While we support value-based care and lowering the cost of medications for our patients, we believe these demonstration models should not disproportionately focus on physician reimbursement as the main solution to the drug pricing problem.

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\(^8\) Social Security Act (SSA) § 1847B; 42 C.F.R. §§ 414.906 and 414.908.
\(^9\) Such drugs are described in SSA § 1842(o)(1)(C).
\(^10\) 81 FR 13230
Innovation is Not Contingent Upon High List Prices

Pharmaceutical research and development is critical to neurologists and their patients. However, high drug costs are not required to support development and we encourage this Administration to dispel the myth that lower drug prices will inherently jeopardize the robust US innovation and development pipeline. Taxpayer-funded research has supported every single one of the 210 drugs approved in the US between 2010 and 2016. Our current drug pricing system charges taxpayers for innovation twice – first via their taxes and again when they pay for a given medication – while manufacturers continue to protect profits and keep prices high. The AAN would support increased transparency and disclosures from manufacturers on the amount of taxpayer-funded research supporting their products.

Physicians Need Tools to Support Patient Financial Health

Physicians lack resources to understand the costs of the medications they prescribe to their patients. Adjustments to list prices, formularies, and insurer policies create an environment where most physicians are unable to even estimate the actual cost of medications for their patients.

The lack of information and transparency in the current system makes patient drug costs unknowable for physicians. For some neurologic conditions, a physician may have several drugs that are relatively equal in efficacy for a patient but have drastically different prices. Neurologists have no way to determine the medication that is best for a patient’s physical health and best for the patient’s financial wellbeing. Frequent changes in drug costs also mean that a medication that was affordable for a patient one month may no longer be affordable the next. Medications for MS provide examples of the lack of transparency in our current system. The prices for some of these drugs have increased by more than 1,000 percent since coming to market in the late 1990’s, but there have been no changes or improvements to those drugs.\(^\text{11}\) MS patients now face annual costs exceeding $90,000 for the exact same medications they were receiving 20 years ago at one tenth of that price. As new options come to market, competitor drugs have increased their prices and patients are responsible for the higher costs. Monthly out-of-pocket costs for MS patients rose from a mean of $7 in 2004 to $303 in 2016. For MS patients in high deductible health plans, monthly out-of-pocket costs were even greater at $686.\(^\text{12}\)

The AAN is interested in potential solutions to this problem, including the integration of patient-specific drug price and insurance coverage information into the electronic medical record. In a system with greater transparency, physicians could more easily consider patient cost in their prescribing decisions. However, for neurologic diseases where all medications are equally expensive, physicians and patients should not be held responsible for high list prices set by manufacturers. Any drug pricing information for physicians must be readily available and easily accessible at the point of prescribing.

The AAN Proposes Ombudsperson for Drug Pricing

HHS currently lacks a staff member whose sole focus is reducing pharmaceutical prices. The AAN recommends that HHS commission a study on the creation of a pharmaceutical pricing ombudsperson. The AAN believes a pharmaceutical pricing ombudsperson would act as an internal expert within the agency to engage with external stakeholders, bring the patient and provider experience with high pharmaceutical prices to the attention of internal policymakers, and serve as an objective and informed source of information for agency staff and Congress. Consistent with the agency’s objectives, the ombudsperson could review stakeholder complaints, analyze pharmaceutical pricing data, identify targeted areas for investigation, and develop recommendations for CMS and HHS on policies to improve prescription drug affordability. Additionally, the AAN believes that centralization of efforts to lower

\(^\text{11}\) House Committee on Oversight and Government Reform. Investigation of Drug Companies’ Skyrocketing Prices for MS Drugs.

\(^\text{12}\) AAN Health Services Research Subcommittee.
pharmaceutical prices within a single office would allow for greater policy coordination and improved communication between the agency and those most impacted by high drug prices.

There is precedent for the establishment of an ombudsperson within HHS and CMS with a mandate to work with external stakeholders and develop recommendations related to a specific policy domain. There are currently fourteen ombudspersons that work within the HHS family of agencies. These ombudspersons investigate complaints, resolve disputes, and collaborate with external stakeholders on concerns related to their issue area. Based on their engagement with external stakeholders, some ombudspersons are empowered to share information and provide recommendations to Congress, the Secretary of Health and Human Services, and other agency policymakers. Examining existing ombudspersons positions within HHS could be informative when establishing guidelines for the activities and objectives of the new position.

The AAN believes that the office of the Medicare Beneficiary Ombudsperson could be an informative model to guide the creation of a pharmaceutical pricing ombudsperson position. The Medicare Beneficiary Ombudsperson’s objectives of advocating for fairness in the Medicare program, bringing the beneficiary experience to the attention of policymakers, and serving as an objective and informed source of information could serve as a standard for the creation of objectives for the pharmaceutical pricing ombudsperson. By utilizing this model, the AAN believes that HHS could effectively consolidate agency initiatives related to prescription drug affordability and amplify impact on this key priority.

Thank you for the opportunity to comment on prescription drug pricing. Please contact Amber Stock, Manager of Advocacy, at astock@aan.com, or Daniel Spirn, Senior Regulatory Counsel, at dspirn@aan.com, with any questions or requests for additional information.

Sincerely,

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